

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 10/674,653 Confirmation No.: 4786
Appellants : Marc E. Feinberg
Filed : September 30, 2003
For : TISSUE APPROXIMATION DEVICE
TC/Art Unit : 3773
Examiner : Melissa K. RYCKMAN
Docket No. : ETH-5092
Customer No.: 25570

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

REPLY BRIEF UNDER 37 C.F.R. §41.41

Dear Sir:

Responsive to the Examiner's Answer mailed December 23, 2011, Appellants submit the following Reply Brief. In view of the Examiner's refusal to enter Appellants' proposed amendment under 37 C.F.R. 41.33(a), Appellants include herewith a corrected version of the appealed claims in the Claims Appendix.

Arguments begin on page 3 of this document.

This Reply Brief addresses certain comments in the Examiner's Answer and, except as otherwise noted herein, is not intended to replace the arguments

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previously set forth in the Appeal Brief. Silence with respect to any issue in this Reply Brief does not signify acquiescence in the Examiner's position; rather, in such cases, Appellants rely on the arguments already set forth in the Appeal Brief.

ARGUMENT

In order to preserve issues on appeal in view of *Ex parte Njo and Sedor*, Appeal No. 2009-004173 (BPAI 2010), Appellants provide the following responses to the Examiner's assertions and conclusions as set forth in the Examiner's Answer issued December 23, 2011 as to the present application.

Initially, Appellants request leave to present a first instance of substantive arguments against the Examiner's formal rejection of claims 38-42 in this Reply Brief, in view of the Examiner's delay (more than three months) in responding to Appellants' proposed amendment under 37 C.F.R. 41.33(a).

In response to Appellants' previous Appeal Brief (July 30, 2010), the Examiner issued an Office Action offering to reopen prosecution (April 27, 2011), in which the formal rejection of claims 38-42 under 35 U.S.C. §112, first paragraph was first raised. As stated in Appellants' response under 37 C.F.R. 41.33(a), Appellants noticed that claims 38-42 were not rejected over prior art, and attempted to cure the formal rejection by submission of their proposed amendment on September 6, 2011, in combination with a second Appeal Brief on even date therewith, containing arguments against the prior art rejection of claims 5, 6, 8 and 46-48. The amendment was submitted in order to reduce the issues remaining for appeal.

The Examiner failed to respond to the proposed amendment under 37 C.F.R. 41.33(a) until the issuance of an Advisory Action on December 21, 2011, denying entry of Appellants' proposed amendment. The Advisory Action was closely followed by the Examiner's Answer, issued on December 23, 2011.

Appellants believe that their proposed amendment should have been treated in accordance with the procedures set forth for issuance of an Advisory

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Action to an amendment submitted under 37 C.F.R. 1.116, pursuant to MPEP 714.13 (III), and as such the Advisory Action should have been issued within thirty (30) days of the date of the proposed amendment. Under these circumstances Appellants would have had an opportunity to file a revised Appeal Brief to address the substantive issues raised by the formal rejection.

Accordingly, this Reply Brief is Appellants' first opportunity to provide a substantive response to the Examiner's reasons for the formal rejection, in view of the delay between the filing of Appellants' proposed amendment (September 6, 2011) and the Examiner's refusal to enter the proposed amendment (December 21, 2011), over three months later.

The Board's consideration of these arguments is respectfully requested.

The Rejections

I. Claims 38-42 stand rejected under 35 U.S.C. §112, first paragraph as exceeding the scope of enablement provided by the specification.

In view of the Examiner's refusal to enter the proposed amendment under 37 C.F.R. 41.33(a), Appellants provide the following comments in traverse of the rejection.

At page 3 of the final Office Action, the Examiner indicates:

The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Line 17 of Claim 38 states "the connector is a rotatable connector", the current specification and current drawing do not enable this, the connector as shown in the drawings, is element 139 in Fig. 7, element 139 does not rotate as it is fixed to arm. (Emphasis added).

Appellants submit that the Examiner's claim construction is unduly limiting, by referring to only a specific illustration, i.e. Fig. 7. The Examiner's statement appears to suggest that the term "connector" is limited to element at 139 in Fig. 7. However, neither the language of claim 38, nor the description in the specification is so limiting. In describing the "connector", claim 38 states in pertinent part:

a pair of arms, each arm having a longitudinal axis and opposed ends, wherein one end includes a handle and the other end includes a tong with a connector;

an adhesive pad removably coupled to the connector of each tong, ... wherein the connectors support the adhesive pads to be positionable in a common plane on opposed sides of the wound and conform to the skin surface adjacent to the wound...

There is nothing in claim 38 which specifies that the "connector" is or should be limited to element 139 of Fig. 7, as suggested by the Examiner.

Further, one skilled in the art would readily recognize the term "connector", as used in the claim, to refer to the entire connection between the adhesive pads and the tongs, i.e. the ball and socket connectors.

Appellant is clearly entitled to have the whole of his disclosure considered [in determining enablement]. (*In re Anderson*, 471 F.2d 1237, 176 USPQ 331, 333 (CCPA 1973)).

Appellants submit that the characterization of the ball and socket connector described in claim 38 as being a "rotatable connector" would have been well-understood by the skilled artisan. Ball and socket connectors are known to be designed and used to provide a certain degree of rotation between two elements connected thereby. Further, at page 4, lines 23-31 of the present specification, Appellants state:

As discussed above, the tissue approximation device may be a pair of forceps where the tongs accommodate the adhesive pad. The adhesive pad may be pre-assembled, or may be fixedly attached to or detachable from the distal end of each of the tongs. The adhesive pads may have a first adhering surface and a second surface having a socket mechanism that communicates with a ball on the distal end of each of the tongs, and the adhesive pad is optionally rotatable around the ball; or the second surface of the adhesive pad may have a ball that communicates with a socket assembly on the distal end of each of the tongs as shown in FIGS. 7 and 8. (Emphasis added).

The patent law regarding written description and enablement does not require that a claim term be present *in ipsis. verbis*:

The PTO has done nothing more than to argue lack of literal support, which is not enough. If lack of literal support alone were enough to support a rejection under § 112, then the statement of In re Lukach, supra, 58 CCPA at 1235, 442 F.2d at 969, 169 USPQ at 796, that "the invention claimed does not have to be described in ipsis verbis in order to satisfy the description requirement of § 112," is empty verbiage. The burden of showing that the claimed invention is not described in the specification rests on the PTO in the first instance, and it is up to the PTO to give reasons why a description not in ipsis verbis is insufficient. *In re Wertheim*, 541 F.2d 257, 265, 191 U.S.P.Q. 90, 98 (CCPA 1976).

Accordingly, Appellants submit that the Examiner's claim construction is in error, as unduly limiting the alleged scope of the claims by referencing Fig. 7, without consideration of the application as a whole, and that the term "rotatable connector" would have been well-understood by the skilled artisan to include both the ball and socket portions of the connection between the tongs and the adhesive pads, as claimed herein.

Reversal of this rejection is courteously solicited in view thereof.

II. Claims 5, 6, 8, and 46 through 48 stand rejected under 35 U.S.C. §103(a) as obvious over Hasson, U.S. Patent No. 4,724,838, in view of Taylor et al., U.S. Patent No. 6,394,951.

In response to Appellants arguments set forth in the Appeal Brief, the Examiner states:

Regarding claim 8: The Appellant argues Hasson fails to teach the device wherein when in the closed position the pads are non-contiguous to each other. The examiner's response is that the claims do not state what the closed position consists of (for further clarification, the application does not define the closed position by stating, for example, that "the device is in the closed position when it is locked by the locking means" and even if this was the case when element 64 in Fig. 7 is locked on the first tab the pads are non-contiguous). The device of Hasson would be considered "closed", for example, when fully engaged with tissue and in this instance the pads are noncontiguous to each other because the tissue is between them. (Examiner's Answer, page 5; emphasis added).

Appellants submit that the Examiner's interpretation of Hasson fails to consider the clear teaching therein that the forceps blades thereof are "closable at their distal ends" (Abstract). The Examiner's failure to consider the Hasson reference "as a whole" constitutes impermissible picking and choosing from the reference only that which supports the rejection, contrary to the patent law.

It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art. *In re Wesslau*, 147 USPQ 391, 393 (CCPA 1965).

A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). **MPEP** 2141.03 VI. (Emphasis added).

Claim 8 specifically indicates:

... the tissue approximation device has an open and a closed position, and when in the closed position, the adhesive pads are parallel and non-contiguous to each other... (Emphasis added).

Thus, it would have been clear to the skilled artisan that the presently claimed device is not "closable at [its] distal ends", according to the language of Hasson. Thus, Appellants submit that the Examiner's posed hypothetical with respect to Fig. 7 of Hasson totally ignores the portion of Hasson which teaches away from the presently claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc., Id.*

Reversal of the rejection is requested on this basis.

Beginning at page 7 of the Examiner's Answer, the Examiner states:

Regarding claim 46: The Appellant argues Hasson does not have "the second surface has the socket and the distal end (of the elongate arm) has the ball". The examiner points to Fig. 14 and col. 5, ll. 11, element 301 is the ball that is mounted onto 12 (the distal end of the elongate arm) and the socket 302 is on the second surface via element 303, in Fig. 14. (Emphasis added).

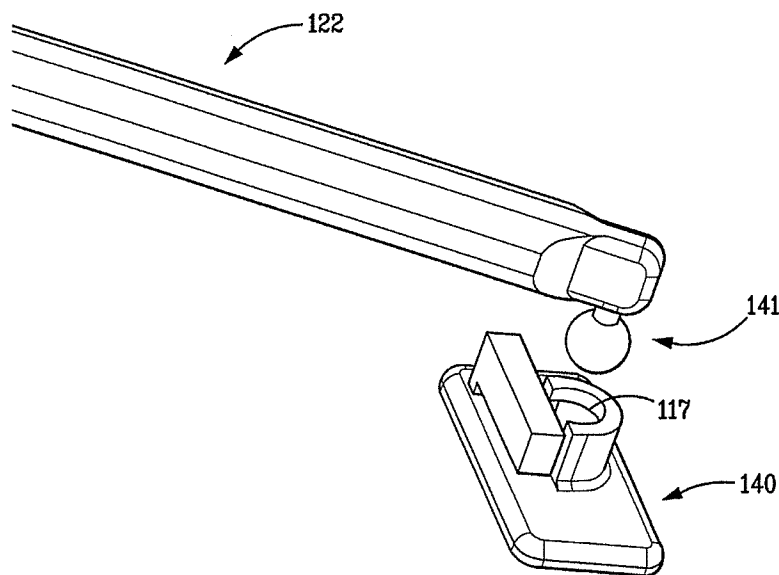
Again, Appellants traverse the Examiner's claim construction, and direct the Board's attention to the actual language of claims 8 and 46 which describes the relationship of the socket and the second surface of the adhesive pads:

... wherein the second surface has one of a socket and a ball that communicates with the other one of a ball and a socket on the distal end of each of the elongate arms...(Claim 8, emphasis added).

The language of claim 8, incorporated into claim 46, clearly indicates that the second surface of the adhesive pad "has...a socket", not a socket mounted to it and offset from it by another claim element, contrary to the Examiner's contention. In this regard, Appellants believe that the claim language is clear on its face. However, in the event the Board would even consider the Examiner's contention, Appellants submit that the patent law requires consideration of the specification when the PTO is construing a questionable claim term.

"Claims are not to be read in a vacuum, and limitations therein are to be interpreted in light of the specification in giving them their 'broadest reasonable interpretation'." *In re Marosi*, 710 F.2d 799, 802 (Fed. Cir. 1983), (quoting *In re Okuzawa*, 537 F.2d 545, 548, 190 USPQ 464, 466 (CCPA 1976)) (emphasis in original). **MPEP 2111.01 (II)**.

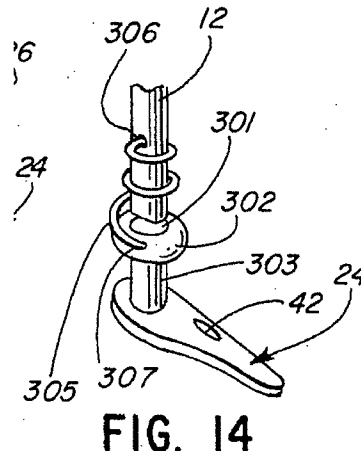
Upon review of the present specification, and Fig. 12 (submitted in Appellants' response of February 12, 2010 and entered by filing a Notice of Appeal on April 9, 2010), reproduced below for the Board's convenience, Appellants submit that the Examiner's contentions as to the actual claim language being broad enough to encompass the structure in Fig. 14 of Hasson is entirely unreasonable.



The amended paragraph describing the embodiment of Fig. 12 states:

Alternatively, as shown in Fig. 12, the ball 141 can be disposed on the distal end of flex arm 122, and recess 117 forming the socket recess (not shown) can be disposed on the second surface of the adhesive pads 140. (Specification, page 9, beginning at line 23; see page 3 of Appellants' response of February 12, 2010; emphasis added).

Appellants submit that no reasonable interpretation of either Fig. 12, *per se*, or the language in the specification describing this embodiment, could encompass the Hasson device illustrated in Fig. 14, and described at col. 5, lines 11-13 of the reference (reproduced below).



In FIG. 14 a ball 301 is mounted on the end of blade 12 with a socket 302 mounted on the stub 303 of a blade fixed to the foot 34. (Emphasis added).

Reversal of the rejection is requested, due to the Examiner's improper claim construction.

At page 8 of the Examiner's Answer, with respect to Appellants' arguments against the rejection of claim 47, the Examiner states:

Regarding claim 47: The Appellant argues it would not have been obvious to rearrange the ball and socket in the device. The examiner maintains the rejection above. The specification (page 3, ll. 1-4) of the current application lists various embodiments including rearranging the ball and socket location. There is no advantage in the specification associated with the placement of the ball and socket. (Emphasis added).

Appellants submit that the Examiner's statement mischaracterizes their argument. In the Appeal Brief, Appellants argued that, even if modified according to the Examiner's proposal, the Hasson device would fail to meet each

and every claim limitation, and therefore fail to establish a *prima facie* case of obviousness. Appellants stated:

As discussed above, Figure 14 of Hasson fails to illustrate an embodiment wherein the socket portion of a ball and socket coupler is disposed on the top (second) surface of foot 24. Instead, the socket is offset from the top surface of the foot 24 by stub 303. Mere rearrangement of the Hasson device, as suggested by the Examiner, would result in the ball 301 being disposed on the upper end of stub 303, and not on the surface of foot 24.

Accordingly, even if modified in the manner suggested by the Examiner, the prior art would not meet each and every limitation of claim 47, as required by the patent law. No *prima facie* case of obviousness can be established. *In re Wada and Murphy, Id.* (Appeal Brief of September 27, 2011; page 20).

Thus, the Examiner's characterization of Appellants' arguments as merely suggesting such rearrangement of the elements would not have been obvious obfuscates Appellants' actual argument. Reversal of the rejection is requested on this basis.

Also at page 8, the Examiner expands on her interpretation of the term "snap-fit" in claim 48:

Regarding claim 48: The Appellant argues Hasson fails to teach the ball and socket are snap-fit. The examiner's position is the act of putting the ball into the socket is snap-fitting the two together. In addition, the spring 305 in Fig. 14 aids in the snap fit of the ball and socket together. The claim does not provide structure for "snap fit" and Hasson teaches the structural limitations required by the claim. (Emphasis added).

In stating her "position", the Examiner merely restates her conclusion, rather than answering Appellants' contentions with respect to the failure of Hasson to inherently disclose a snap-fit connection.

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Hasson is entirely silent as to any particular socket design, and the illustration in Figure 14 (item 302) is only schematic, such that the specific design is not apparent.

Further, the only indication as to materials of construction of the Hasson device is set forth at column 3, lines 8-10, wherein patentee discloses that the blades can be made of "metal or like material". If the same is true of the ball (at the end of the blades) and socket joint, one skilled in the art would recognize that a metal ball and socket joint usually necessitates heating of the socket so as to expand it sufficiently to permit insertion of the ball, since the upper circumference of the socket surrounds the upper circumference of the ball. Thus, the socket portion of Hasson is not necessarily flexible enough to permit a snap fit insertion of the ball.

Accordingly, Appellants submit that the Examiner has factually erred, in that Hasson fails to disclose a snap fit ball and socket joint, and legally erred by apparently assuming that all ball and socket joints are inherently snap fittable. (Appeal Brief of September 27, 2011; pages 22-23; emphasis in original).

Additionally, regarding the Examiner's contention that the claim fails to provide structure for the term "snap-fit", Appellants again submit that the Examiner's claim construction is not reasonable in light of the specification. *In re Marosi, Id.* Review of the present specification provides an example of a "snap-fit" connection:

As shown in FIGS. 7 and 8, tongs 112b and 114b include a recess 117, 119 that allows flex arm 121, 122 to deflect when ball 131, 141 of adhesive pad 130, 140 is installed into socket recess 138, 139. (Specification, page 9, lines 23-25).

Likewise, Appellants submit that the term "snap-fit", while admittedly somewhat functional, would readily inform those skilled in the art of the nature of the connection.

Accordingly, Appellants submit that in view of either the specification example, or the skill in the art, the claim limitation would have been readily understood without the necessity of specific structure in the claim.

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Reversal of the rejection is requested on these bases.

CONCLUSION

In view of the foregoing, it is respectfully submitted that the present claims are in condition for allowance. The Board of Appeals is respectfully requested to remand this application to the Examiner with a direction to allow the claims.

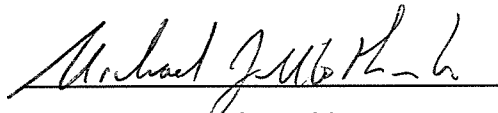
If necessary to effect a timely response, this paper should also be considered as a petition for an Extension of Time sufficient to effect a timely response.

Please charge any deficiency in fees or credit any overpayments to Deposit Account No. 50-2478 (14851).

If the Board has any questions or wishes to discuss this application, the Examiner is invited to contact the undersigned representative at the number set forth below.

Respectfully submitted,

Date: February 23, 2012



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CLAIMS APPENDIX (Revised)

5. The tissue approximation device of claim 8, where the elongate arms form a pair of forceps, the attachment means is a yoke on the forceps, and the locking means is a ratchet mechanism on the forceps.

6. The tissue approximation device of claim 5, where the distance between the elongate arms is adjustable by means of a ratchet mechanism.

8. A tissue approximation device comprising two elongate arms having proximal and distal ends, an attachment means to secure the elongate arms to each other at one or more locations, adhesive pads movably connected on the ends of the elongate arms to anchor the tissue approximation device to the skin, and a locking means to lock the elongate arms in place relative to each other, wherein (i) the adhesive pads are spaced apart from the one or more locations of the attachment means in the direction of the elongate arms, and (ii) the tissue approximation device has an open and a closed position, and when in the closed position, the adhesive pads are parallel and non-contiguous to each other, where the adhesive pad has a first adhering surface and a second surface rotatably coupled to the distal end of each of the elongate arms by a ball and socket connector, wherein the second surface has one of a socket and a ball that communicates with the other one of a ball and a socket on the distal end of each of the elongate arms, and the adhesive pad is rotatable around the ball and socket connector about at least two axes.

38. A tissue approximation device for application to a skin surface adjacent to a wound, comprising:

 a pair of arms, each arm having a longitudinal axis and opposed ends, wherein one end includes a handle and the other end includes a tong with a connector;

an attachment mechanism coupled to each arm that movably couples the arms to each other so that a distance between each tong is selectively variable;

an adhesive pad removably coupled to the connector of each tong, wherein each adhesive pad has an adhesive surface that extends in a plane generally parallel to the longitudinal axis of the respective tong, the adhesive surface having a high shear resistance for holding the skin surface and a low peel resistance for removal from the skin surface, and wherein the connectors support the adhesive pads to be positionable in a common plane on opposed sides of the wound and conform to the skin surface adjacent to the wound; and

a locking mechanism coupled to each arm to selectively lock the pair of arms in a fixed position relative to each other,

wherein the connector is a rotatable connector that connects the adhesive pad to the tong to pivot at least about the longitudinal axis and an axis substantially perpendicular to the longitudinal axis and the rotatable connector is one of a ball and a socket and the adhesive pad includes the other of the ball and the socket, wherein the ball and socket are snap fit together in an interference fit.

39. The device of claim 38, wherein the arms are connected in a scissors configuration.

40. The device of claim 38, wherein the adhesive pad includes serrations that provide flexibility to the adhesive surface.

41. The device of claim 38, wherein the locking mechanism includes a ratchet.

42. The device of claim 38, wherein the arms are made of a resilient material.

46. The device of claim 8, wherein the second surface has the socket and the distal end has the ball.

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47. The device of claim 8, wherein the second surface has the ball and the distal end has the socket.

48. The device of claim 8, wherein the second surface and the distal end of the elongate arm connect in a snap fit manner.